

Millistak+® Mini

Grade C0 of  
Series HC Depth Filter  
Catalogue Number: MC0HC23HH3  
Lot Number: C9KN18879

#### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

#### ISO 9000 Quality Standard

This product was manufactured in a facility whose quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

#### Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

#### Indirect Food Additives

All component materials meet the FDA Indirect Food Additive Requirements cited in 21CFR 177.186.

#### Quality Assurance Lot Release Criteria

The filter material used in this manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

##### USP Bacterial Endotoxins

An aqueous extraction contained less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

##### Flow Rate and Pressure Drop

Media samples met a pressure drop versus flow rate specification that correlates to a capsule flow rate of 90.3-101.8 L/min/m<sup>2</sup> at 10 psid (690 mbar) with clean water at 23 °C.

##### Thickness

Samples measured met the required thickness  
Media Layer 30DE: 0.125-0.145 in.  
Media Layer 60DE: 0.125-0.145 in.

##### Basis Weight

The basis weight of samples tested were within  
Media Layer 30DE: 756-1195 g/m<sup>2</sup>.  
Media Layer 60DE: 882-1320 g/m<sup>2</sup>.

##### Ash Content

Ash content was determined to be  
Media Layer 30DE 49-59%.  
Media Layer 60DE 48-58%.

##### Wet Tensile Strength

Wet tensile strength of the samples tested was  
Media Layer 30DE: ≥ 10 lb/in.  
Media Layer 60DE: ≥ 10 lb/in.

#### Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

##### Oxidizable Substances

Aqueous effluent was negative after a water flush of 5 L per square foot of media.

##### Multiple Sterilization Cycles

Integrity was maintained after 1 autoclave cycle of 60 minutes at 123 °C.

Peter Eichert  
BioPharmaceutical Quality Manager

